

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ERIC D. BLOM,
W. GREGORY CHERNOFF
and DANIEL W. KARAKLA

Appeal No. 2002-2187
Application 09/149,359

ON BRIEF

Before STAAB, MCQUADE, and CRAWFORD, Administrative Patent Judges.

MCQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Eric D. Blom et al. originally took this appeal from the final rejection (Paper No. 13) of claims 7 through 13 and 17 through 19, all of the claims pending in the application. As the examiner has since withdrawn all rejections of claims 10 through 13, the appeal as to these claims is hereby dismissed, leaving for review the standing rejections of claims 7 through 9 and 17 through 19. Claims 11 through 13 stand allowed and claim 10 stands objected to as depending from a rejected base claim.

THE INVENTION

The invention relates to a method for inserting a medical device into an opening in a human body. Representative claims 7 and 17 read as follows:

7. A method for inserting into a first opening in a human body a device including a device body having a longitudinal axis and a flexible first flange provided on an outside surface of the device body, the flange having a continuous radially-extending surface which extends radially outward from the body to a radial outer edge of the flange and having a deployed, use orientation in which it projects generally outwardly from the outside surface of the device body comprising resiliently deflecting the flange toward the axis of the device body and placing over the resiliently deflected flange a retainer of a material soluble in a fluid, inserting the device into the first opening, and permitted dissolution of the retainer.

17. A method for inserting into an opening in a human body a device including a resiliently deflectable device body having a substantially uniform insertion cross-section transverse to its longitudinal extent which is insufficient to fill the opening and a larger use cross section transverse to its longitudinal extent, the method comprising resiliently deflecting the device body into it substantially uniform insertion cross-section, placing over the resiliently deflected device body a retainer for retaining the device body in its substantially uniform insertion cross section, inserting the device with the retainer in place into the opening, and removing the retainer to permit deployment of the device body to its use cross section.

THE PRIOR ART

The references relied on by the examiner to support the final rejection are:

Bruce et al. (Bruce)	4,695,275	Sep. 22, 1987
Blom et al. (Blom)	4,911,716	Mar. 27, 1990

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Bouton et al. (Bouton)	4,964,850	Oct. 23, 1990
Shikani	5,246,455	Sep. 21, 1993

THE REJECTIONS

Claims 17 through 19 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a specification which fails to comply with the written description requirement of this section of the statute.

Claims 17 through 19 stand rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter the appellants regard as the invention.

Claims 17 and 18 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Shikani.

Claims 17 through 19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Blom.

Claims 17 and 18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by, and in the alternative under 35 U.S.C. § 103(a) as being unpatentable over, Bouton.

Claims 17 and 18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by, and in the alternative under 35 U.S.C. § 103(a) as being unpatentable over, Bruce.

Claims 7 through 9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by, and in the alternative under 35 U.S.C. § 103(a) as being unpatentable over, Blom.

Attention is directed to the main and reply briefs (Paper Nos. 15 and 18) and to the answer (Paper No. 17) for the respective positions of the appellants and the examiner regarding the merits of these rejections.¹

DISCUSSION

I. The 35 U.S.C. § 112, first and second paragraph, rejections of claims 17 through 19

These rejections stem from the examiner's concern (see page 5 in the answer) that the recitation in independent claim 17 of the insertion cross-section of the resiliently deflectable device body as being "substantially" uniform lacks written descriptive support in the underlying specification and, as a consequence, also renders the scope of the claimed subject matter indefinite.

Claim 17, and claims 18 and 19 which depend therefrom, pertain to the nasal packing insertion method disclosed by the appellants on pages 13 and 14 in the specification and in Figures

¹ The final rejection also contained a provisional obviousness-type double patenting rejection of claims 7 through 13 and 17 through 19, § 102(b) and § 103(a) rejections of claims 9 and 10 based on Bouton, and § 102(b) and § 103(a) rejections of claim 9 based on Bruce. The examiner has since withdrawn all of these rejections (see pages 2 through 4 in the answer).

17 and 18 of the drawings.² Page 13 in the original specification indicates that resiliently deflectable device bodies of the sort set forth in claims 17 through 19, i.e. nasal packings 224, "are compressed and inserted into thin-walled, sleeve-like, flexible gelatin retainers 226," and that "[t]he packing 224 - retainer 226 combination is flexible and of small enough cross sectional area, for example, to be inserted easily through nostril 220 into nasal cavity 222 without causing significant trauma." Original Figure 18 depicts the insertion step.

The written description requirement of 35 U.S.C. § 112, first paragraph, requires the disclosure of the application as originally filed to reasonably convey to the artisan that the inventors had possession at that time of the later claimed subject matter. In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983). The content of the drawings may be considered in determining compliance with the written description requirement. Id. The second paragraph of 35 U.S.C. § 112

² The appellants' assertion on page 11 in the main brief that these claims also relate to the voice prosthesis and septal button insertion methods described and illustrated elsewhere in the disclosure is not well taken. The limitations in these claims, viewed in light of the underlying disclosure, simply do not read on these other embodiments (in accord is the summary of the invention set forth on pages 3 through 7 in the main brief).

requires claims to set out and circumscribe a particular area with a reasonable degree of precision and particularity. In re Johnson, 558 F.2d 1008, 1015, 194 USPQ 187, 193 (CCPA 1977). In determining whether this standard is met, the definiteness of the language employed in the claims must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. Id.

Although the appellants' original disclosure does not furnish literal support for the claim limitation at issue, its description that the nasal packings are compressed and inserted into thin-walled, flexible gelatin retainers, as well as the depiction thereof in the drawings, would reasonably convey to the artisan that the appellants had possession at that time of a method as recited in claims 17 through 19 wherein the insertion cross-section of the resiliently deflectable device body (nasal packing 224) is "substantially" uniform. Also, read in light of this description, the "substantially" uniform limitation sets out and circumscribes the insertion cross-section of the resiliently deflectable device body with a reasonable degree of precision and particularity.

Accordingly, we shall not sustain the standing 35 U.S.C. § 112, first and second paragraph, rejections of claims 17 through 19.

III. The 35 U.S.C. § 102(b), 102(e) and 103(a) rejections of claims 7 through 9 and 17 through 19

The references applied in support of these rejections pertain to medical devices having flanges which can be deformed or deflected to facilitate insertion of the devices into a patient's body.

Shikani discloses a middle meatal antrostomy ventilation tube 10 comprising a central tubular section 12 having a rectangular flange 22 fitted onto one end and a triangular flange 34 fitted onto the other end. As described in the reference,

[i]nsertion of the ventilation tube 10 is performed by grasping the two long sides 30, 32 of the elongated rectangular flange 22 and folding them over until they lie in parallel relation 40, 42 to the side of the central tubular section 12, whereupon they may be securely grasped with a hemostat or forceps. . . . With the visual assistance of an endoscope (not shown), the hemostat or forceps can then be used to advance the ventilation tube 10 up the nasal passage 50 to a site where an antrostomy opening has been prepared in the lateral nasal wall. The triangular flange 34 is angularly urged through this antrostomy until fully inserted within the nasal sinus 52, whereupon it comes to rest against the lateral nasal wall 48 (i.e., the medial wall of the maxillary sinus), with the middle turbinate 46 free to bump against it. The elongated rectangular flange 22 rests upon the opposite surface

of the medial wall of the maxillary sinus [column 3, line 54, through column 4, line 34].

Blom discloses a helical coil spring implant 400 for retaining a voice prosthesis. The implant has a diamond shape end portion 404 extending therefrom which acts as a flange to hold the implant in its intended position. With regard to the method of implantation, Blom teaches that

end portion 404 of implant 400 is deflected sufficiently to insert it into half 416 of a gelatin capsule. Implant 400 is inserted as far as it will go into capsule 416 and a standard insertion tool is then inserted into implant 400 and the implant is inserted into the fistula 408. Saliva and mucus dissolve the half gelatin capsule 416 and end portion 404 springs back to its undeflected orientation [column 10, lines 5 through 12].

Bouton discloses a flexible plastic sinus aerator comprising a hollow tube 1 having two wings/flanges 2a and 2b attached at one end and two wings/flanges 3a and 3b attached at the other end. According to Bouton, the aerator is positioned within a puncture in the inferior nasal meatus by a delivery device 5 (see Figure 2) or a bent pliers inserter 7 (see Figure 4) which function to fold the wings/flanges 3a and 3b to allow insertion through the puncture.

Bruce discloses a middle ear ventilation tube comprising a tubular body 10 having a flange 14 on one end and two lateral arms/flanges 16 on the other end. Bruce indicates that the tube

is inserted through an incision in the tympanic membrane 20 by using alligator forceps 23 to grasp and fold the arms/flanges 16 toward one another to allow them to be inserted through the incision whereupon they are allowed to spring back to their normal lateral position to engage the membrane when the forceps are released.

With regard to the various prior art rejections of claims 17 through 19, the examiner relies on the deformable or deflectable flange structures respectively disclosed by the foregoing references as responding to the limitation in claim 17 requiring a resiliently deflectable device body "having a substantially uniform insertion cross-section transverse to its longitudinal extent." In short, however, none of Shikani's rectangular flange 22, Blom's diamond shape end portion 404, Bouton's wings 3a and 3b, or Bruce's lateral arms 16 teaches or would have suggested this feature. The examiner's additional determination that Blom's helical coil spring implant 400 constitutes a resiliently deflectable device body having a substantially uniform insertion cross-section transverse to its longitudinal extent because "the cross-section taken along the diameter of the tube is reduced by the deflection step . . . [o]therwise, it would not fit within the capsule, which is the same diameter as the coil spring tube"

(answer, pages 10 and 11) finds no factual support in the fair teachings of Blom.

As for the prior art rejections of claims 7 through 9 based on Blom, notwithstanding the examiner's apparent finding to the contrary (see pages 7, 12 and 13 in the answer), a person of ordinary skill in the art would not reasonably view the diamond shape end 404 extending from Blom's surgical implant 400 as constituting flange "provided on an outside surface of the device body" and having "a continuous radially-extending surface which extends radially outward from the body to a radial outer edge of the flange" as recited in independent claim 7, or as being suggestive of such. Although the diamond shaped end 404 embodies a flange, a person of ordinary skill in the art would not view its wire like construction extending from the end of the implant as being on the outside surface of the implant or device body or as defining a continuous radially-extending surface which extends radially outward from the body to a radial outer edge of the flange.

In light of the foregoing, we shall not sustain the standing 35 U.S.C. § 102(e) rejection of claims 17 and 18 based on Shikani, the standing 35 U.S.C. § 102(b) rejection of claims 17 through 19 based on Blom, the standing 35 U.S.C. § 102(b) and

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103(a) rejections of claims 17 and 18 based on Bouton, the
standing 35 U.S.C. § 102(b) and 103(a) rejections of claims 17
and 18 based on Bruce, or the standing 35 U.S.C. § 102(b) and
103(a) rejections of claims 7 through 9 based on Blom.

SUMMARY

The decision of the examiner to reject claims 7 through 9
and 17 through 19 is reversed.

REVERSED

LAWRENCE J. STAAB)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
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)	APPEALS AND
JOHN P. MCQUADE)	
Administrative Patent Judge)	INTERFERENCES
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MURRIEL E. CRAWFORD)	
Administrative Patent Judge)	

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